K010916

PTW-New York Corporation
201 Park Ave., Hicksville, New York 11801
(P) 1-516-827-3181
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JUN 2 0 2001

510(k) Premarket Notification for PTW T60008 Dosimetry Diode

Manufacturer's 510(k) Summary Certification, 21 CFR 807.92(h):

1. **Company:**

PTW-New York Corporation
201Park Avenue
Hicksville, New York 11801
(P) 1-516-827-3181
(F) 1-516-827-3184

Contact:

Stephen R. Szeglin
General Manager
PTW-New York Corporation
(P) 1-516-827-3181
(F) 1-516-827-3184

Date of Submission:
March 7, 2001

2. **Trade/Proprietary Name:**
PTW T60008, Dosimetry Diode

Common/Usual Name:
Diode

3. **Predicate Device(s):**
ISORAD Solid State Diode Detector, K912250, 11 May 1991.

4. **Description of Device(s):**
The T60008 Dosimetry Diode is a p-type Silicon diode encapsulated in a water equivalent plastic. This system was designed in response to numerous requests from the Medical Physics community to provide a highly accurate and precise diode detector to measure the beam characteristics of radiation therapy treatment machines and to map the dose distributions from brachytherapy sources. The Dosimetry Diode is waterproof and it can be used in water phantoms without additional protective sleeves.

5. **Statement of Intended Use:**
The Dosimetry Diode is a p-type Silicon diode designed for dose measurements in high energy photon beams. Applications are IMRT, stereotactic beams, water phantom scanning, and mapping dose distributions from brachytherapy sources. The Dosimetry Diode features a small sensitive volume shaped as a disk with an area of 1 mm^2 and a thickness of only 2.5 µm. This allows the Dosimetry Diode to be used in very small fields and provides excellent spatial resolution during data acquisition. Because of the favorable signal-to-noise ratio, the Dosimetry Diode is suitable for high precision dosimetry measurements. The Dosimetry Diode is waterproof and it can be used in water phantoms without additional protective sleeves.

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6. Comparison of Technological Characteristics to the Predicate Devices:

The intended use of Diode Detector is the same as the ISORAD Solid State Diode Detector, K912250, the predicate device.

The technological specifications of Dosimetry Diode meets or exceeds that of the predicate device.

Safety and effectiveness between the Dosimetry Diode and the predicate device is not an issue since the Dosimetry Diode meets or exceeds all of the applicable requirements of:

IEC 601-1:	Medical Electrical Equipment,
IEC 60601-1-2:	Electromagnetic Emissions,
IEC1010 / EN61010:	Safety Standard,
IEC 1187 / EN61187:	Documentation and content that must accompany the device.

The manufacturing process, procedures, and testing of the Dosimetry Diode exceeds that of the predicate since the Dosimetry Diode meets or exceed ISO 9001 standards which the predicate device does not.

The Dosimetry Diode will be manufactured in compliance with our ISO 9001 certification and will be CE marked with CE 0124, the predicate device is not CE marked.

It is our opinion that the indications for use, design, materials, manufacturing, and specifications of the PTW T60008 Dosimetry Diode do not raise any issues with regard to safety and effectiveness. Hence, PTW considers the T60008 Dosimetry Diode be substantially equivalent in all respects to the predicate device.

Note: Any statement made in conjunction with this Summary regarding substantial equivalence to another product was made in relation to the 510(k) premarket approval process and should not be interpreted as an admission or used as evidence in patient infringement litigation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 0 2001

Mr. Stephen R. Szeglin
General Manager
PTW-New York Corporation
201 Park Avenue
HICKSVILLE NEW YORK 11801

Re: K010916
T60008 Dosimetry Diode
Dated: March 23, 2001
Received: March 27, 2001
Regulatory Class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Mr. Szeglin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K010916

Device Name: PTW Dosimetry Diode, T60008

Indications For Use:

The Dosimetry Diode is a p-type Silicon diode designed for dose measurements in high energy photon beams. Applications are IMRT, stereotactic beams, water phantom scanning, and mapping dose distributions from brachytherapy sources. The Dosimetry Diode features a small sensitive volume shaped as a disk with an area of 1 mm² and a thickness of only 2.5 µm. This allows the Dosimetry Diode to be used in very small fields and provides excellent spatial resolution during data acquisition. Because of the favorable signal-to-noise ratio, the Dosimetry Diode is suitable for high precision dosimetry measurements. The Dosimetry Diode is waterproof and it can be used in water phantoms without additional protective sleeves.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

David A. Segram

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010916

(Optional Format 3-10-98)

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